Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

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REGISTRATION DECISION

Novaluron

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Registration Decision for Novaluron

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting full registration for the sale and use of the technical grade active ingredient novaluron and the end-use product Rimon 10EC to control Colorado potato beetle and European corn borer on potatoes and codling moth and Oriental fruit moth on apples by foliar application.

Current scientific data from the registrant, scientific reports and information from other regulatory agencies were evaluated to determine if, under the conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision PRD2006-05, *Novaluron*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for novaluron as well as summarizes the Agency's decision and the reasons for it. The PMRA received no comments on Proposed Registration Decision PRD2006-05, *Novaluron*, that would impact the risk assessment. The use of novaluron on pears, as detailed in PRD2006-05, is not included as part of the final registration decision resulting from a request by the registrant to remove this use from the product label. This decision is consistent with the proposed registration decision stated in Proposed Registration Decision PRD2006-05, *Novaluron*, with the exception of the use of novaluron on pears.

For more details on the information presented in this Registration Decision, please refer to the science evaluation section of the related Proposed Registration Decision PRD2006-05, *Novaluron*.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration[3]. The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

Rigorous, modern hazard and risk assessment methods and policies are applied to reach decisions. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g., children) and organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process or risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What is Novaluron?

Novaluron is an insect growth regulator for controlling Colorado potato beetle and European corn borer on potatoes and codling moth and Oriental fruit moth on apples by foliar application. Novaluron inhibits chitin synthesis, affecting moulting, but does not affect the adult stage after development is completed.

❖ Health Considerations

♦ Can Approved Uses of Novaluron Affect Human Health?

Novaluron is unlikely to affect your health when used according to the label directions.

Exposure to novaluron may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using products containing novaluron according to the label directions.

The technical grade active ingredient novaluron and the end-use product Rimon 10EC caused eye and skin irritation in animals. As a result, the statement *Warning Eye and Skin Irritant* must appear on the label. Rimon 10EC also caused an immune response when applied on the skin; consequently, the statement *Potential Skin Sensitizer* must appear on the product label. Novaluron did not cause cancer in animals and was not genotoxic. There was also no indication that novaluron caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of novaluron over longer periods of time were indications of damage to red blood cells. The risk assessment protects against these effects by ensuring that the level of

human exposure is well below the lowest dose at which these effects occurred in animal tests.

♦ Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Dietary risk estimates (food and water) revealed that children, adults and seniors will typically consume less than 15.0% of the acceptable daily intake for novaluron. Infants, the subpopulation that would ingest the most novaluron relative to body weight, are expected to eat less than 17.3% of the acceptable daily intake. The dietary intake estimate for females of childbearing age (13 to 49 years old) was about 4.7% of the reference dose, which is not a health concern. Based on these estimates, the chronic dietary risk from novaluron is not a concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of novaluron is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

On-field residue trials conducted throughout Canada, the United States and Europe (France, Spain, Italy and Germany) using an end-use product containing novaluron on apple, pear and potato crops were sufficient to propose MRLs for the pome fruits crop group, which consists of apples, crabapples, loquats, mayhaws, pears, oriental pears and quince, as well as the tuberous and corm vegetables crop group, which consists of arracaha, arrowroot, Chinese artichokes, Jerusalem artichokes, edible canna, cassava roots, chayote roots, chufa, ginger roots, lerens, potatoes, sweet potato roots, tanier corms, taro corms, turmeric roots, yam bean roots and true yam tubers. The MRLs for novaluron can be found in the Science Evaluation section of Proposed Registration Decision PRD2006-05, *Novaluron*.

♦ Occupational Risks From Handling Rimon 10EC

Occupational risks are not of concern when Rimon 10EC is used according to the label directions, which include protective measures.

Pesticide applicators mixing, loading or applying Rimon 10EC and field workers entering freshly treated fields can have direct skin contact with novaluron. For this reason, the label will specify that anyone mixing or loading Rimon 10EC must wear a long-sleeved shirt and long pants, footwear, eye protection and gloves. Because of this and taking into consideration that occupational exposure is expected to be limited as this insecticide is applied up to four times per season, risk to pesticide applicators and workers is not a concern.

Non-occupational risks are not of concern provided that the directions specified on the label are observed.

The risk to people who are exposed to novaluron through diet and when picking apples at commercial farms has been assessed and is not of concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, the health risks to bystanders are not of concern.

❖ Environmental Considerations

♦ What Happens When Novaluron Is Introduced Into the Environment?

Novaluron is toxic to aquatic invertebrates and non-target plants. Untreated areas (buffer zones) adjacent to aquatic and terrestrial plant habitats are required for the protection of these organisms.

Novaluron enters the environment when used as an insecticide on potatoes and apples. Novaluron is slightly persistent in soil and sediments. Its major breakdown products are moderately persistent in these environments. Neither novaluron nor its major breakdown products are mobile in soil and are not expected to leach into groundwater. Based on its low volatility (vapour pressure and Henry's law constant), novaluron residues are not expected in the air.

Novaluron presents high risks to freshwater and marine aquatic invertebrates, and a moderate risk to marine mollusks. There is also some risk to susceptible non-target plant species. Beneficial insects such as predatory mites, parasitoid wasps and honeybees may be temporarily suppressed. Therefore, hazard statements and specific instructions for reducing spray drift to terrestrial insects are provided on the product label. Depending on the type of application equipment, timing of spray and crop, the buffer zones may vary from 3 to 80 metres for freshwater/estuarine aquatic organisms, and from 1 to 30 metres for non-target terrestrial plant species.

❖ Value Considerations

♦ What is the Value of Novaluron?

Novaluron is an insect growth regulator that controls major pests on potato and apple crops.

Foliar application of novaluron controls Colorado potato beetle and European corn borer on potatoes and codling moth and Oriental fruit moth on apples. It is compatible with current management practices and crop production systems. Growers are familiar with monitoring techniques to determine if and when applications are needed.

Novaluron is an alternative to insecticides currently registered to control the same pests on potato and apple crops. This new chemistry is needed for use against Colorado potato beetle, a major pest in potato crops, to prevent the development of resistance to insecticides that are currently available as well as to replace older insecticides, such as organophosphates, for controlling pests in apple crops.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures for Rimon 10 EC Insecticide are as follows:

Key Risk-Reduction Measures

- **Human Health**

Individuals must wear a long-sleeved shirt, long pants, footwear, eye protection and gloves during mixing and loading, clean-up and repair activities. Applicators must wear a long-sleeved shirt, long pants and footwear.

- **Environment**

Buffer zones are required to protect aquatic organisms and non-target plants from Rimon 10 EC spray drift. Depending on the type of application equipment, timing of spray, and crop, the buffer zones may vary from 3 to 80 metres for aquatic organisms and from 1 to 30 metres for non-target terrestrial plant species.

Risks to beneficial terrestrial organisms such as honeybees, predatory mites and parasitoid wasps will be mitigated by use of environmental hazard statements.

Other Information

The relevant test data on which the decision is based (as referenced in Proposed Registration Decision PRD2006-05, *Novaluron*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail pmra_infoserv@hc-sc.gc.ca.

Any person may file a notice of objection[5] regarding this registration decision on novaluron within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the information on Requesting a Reconsideration of Decision on the PMRA's website or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail pmra_infoserv@hc-sc.gc.ca.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.